

Mark H. PAUSCH *et al.*  
Application Serial No. 08/816,011

Attorney Docket No.: 01142.0122

**REMARKS**

**I. STATUS OF THE APPLICATION AND CLAIMS**

Claims 1-33 and 36-39 are pending in this application. Claims 22, 24, 27, 29, 30, and 33 stand rejected. The Office has withdrawn claims 1-21, 23, 25, 26, 28, 31, 32, and 36-39 from consideration as drawn to non-elected inventions. Office Action, page 2.

Applicants have amended claims 24, 27, and 33 solely to more clearly recite their invention. Support for the amendment is found in the claims as originally filed. The amendment does not enter new matter.

Applicants also submit a substitute copy of the Sequence Listing to correct an inadvertent error. SEQ ID NO:4 incorrectly identifies the amino acid sequence as one encoded by a nucleotide sequence isolated from *D. melanogaster*. In fact, the sequence should be identified as an amino acid sequence encoded by a nucleotide sequence isolated from *C. elegans*. This is supported by page 40 of the specification. This inadvertent error was called to the Examiner's attention in a teleconference on January 22, 2003, in relation to U.S. Application No. 09/503,849, which is a continuation-in-part of this application. Applicant respectfully requests entry of this substitute Sequence Listing.

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
www.finnegan.com

Mark H. PAUSCH *et al.*  
Application Serial No. 08/816,011


Attorney Docket No.: 01142.0122

**II. REJECTIONS UNDER 35 U.S.C. § 101 AND 35 U.S.C. § 112,  
FIRST PARAGRAPH, FOR NON-ENABLEMENT**

The Office continues to reject claims 22, 24, 27, 29, 30, and 33 under 35 U.S.C. § 101 as allegedly unsupported by either a substantial asserted utility or a well-established utility. Specifically, the Office asserts that the specification fails to disclose a compound that selectively inhibits nematode pests via the described two pore potassium channel. Office Action, page 2. Thus, the Office concludes that the claimed invention lacks substantial utility because further research would be required to identify or confirm a "real-world" use for the invention.

The Office also rejects the claims under 35 U.S.C. § 112, first paragraph, because it alleges that one of skill in the art would not know how to use the invention since it is not supported by a substantial or well-established utility. Office Action, pages 2 and 3. Applicants respectfully traverse these rejections for the reasons of record, as supplemented below.

The Office's rejection of these claims for lack of a substantial asserted utility or a well-established utility is improper under the Revised Interim Utility Guidelines Training Materials. Example 10 of the Guidelines describes disclosure of a full Open Reading Frame ("ORF") and identification of the corresponding protein sequence, which has high homology to a DNA ligase. The specification also teaches a high degree of sequence conservation among DNA ligases. The hypothetical claim in this example is to "[a]n isolated and purified nucleic acid comprising SEQ. ID. NO. 2." The Guidelines conclude that, based on these facts, there is a well-established utility for the claimed sequence.

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER 

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
[www.finnegan.com](http://www.finnegan.com)

Mark H. PAUSCH *et al.*  
Application Serial No. 08/816,011

Attorney Docket No.: 01142.0122

Likewise, Applicants disclose the nucleotide sequences of the present invention isolated from several species, including human tissue, and note the high level of homology in certain regions of the ORF to other potassium channel nucleotides. Thus, like the hypothetical claim in the Guidelines example, Applicants' claims also have a well-established utility.

In light of Applicants' discussion regarding the well-established and real-world utilities of the present invention, the Office is respectfully requested to withdraw the rejection of claims 22, 24, 27, 29, 30, and 33 under 35 U.S.C. § 101 as allegedly unsupported by either a substantial asserted utility or a well-established utility and to withdraw the rejection under § 112, first paragraph, because of the alleged lack of well-established utility.

**III. REJECTION UNDER 35 U.S.C. § 112,  
FIRST PARAGRAPH, WRITTEN DESCRIPTION REQUIREMENT**

Claims 24, 29, and 33 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter not described in the specification so as to reasonably convey to the person skilled in the art that Applicants were in possession of the claimed invention at the time the application was filed. Specifically, the Office rejects the claims because they allegedly encompass isolated nucleic acids encoding variants and protein fragments via inclusion of hybridization limitations without functional limitation. Office Action, page 3. The Office also asserts that the claims, as amended, contain generic structural limitations without any functional limitation on the class encompassed within claim 24. Applicants respectfully traverse these rejections.

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
www.finnegan.com

Mark H. PAUSCH *et al.*  
Application Serial No. 08/816,011

Attorney Docket No.: 01142.0122

Applicants disagree with the Office's characterization of Claim 24 and claims dependent thereon. The claims are directed to a nucleotide sequence that encodes an amino acid sequence of a *C. elegans* two pore potassium channel. The claims recite nucleic acid sequences that hybridize to SEQ ID NO:36 under high stringency conditions, which the specification describes as sequences having regions of greater than 90% homology to this probe sequence and certain conserved and described nucleotide regions in the first pore-forming domain. See Specification, pages 13, 14, and 21. The claim further incorporates degenerate sequences and functional derivatives, which are both described, for example, on pages 16-18.

The Federal Circuit, in *University of California v. Eli Lilly & Co.*, 43 U.S.P.Q.2d 1398, 1404 (Fed. Cir. 1997), stated that to satisfy the written description requirement for a genus claim, there must be more than a mere statement that particular subject matter is part of the invention. The application as filed discloses and describes several primary nucleotide sequences and has further described the relevant characteristics of other nucleotide sequences that encode two-pore potassium channel proteins. The Applicants have not claimed all nucleic acids encoding all potassium channel proteins, but rather claim nucleic acids that encode functional proteins meeting particular described and claimed conditions.

Applicants have provided sufficient description of claims 24, 29, and 33. Therefore, they respectfully request reconsideration and withdrawal of this rejection.

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNN LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
www.finnegan.com

Mark H. PAUSCH *et al.*  
Application Serial No. 08/816,011

Attorney Docket No.: 01142.0122

**IV. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH**

The Office rejects claim 24 under 35 U.S.C. § 112, second paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter the Applicants regard as the invention. Office Action, page 3. The Office rejects claim 24 as being indefinite in its recitation of non-elected SEQ ID NO:1. Applicants have amended claim 24 to cancel language directed to the non-elected species, thereby obviating this ground of rejection.

The Office also rejects claim 24 as indefinite in its recitation of the term "% homology" rather than using the term "% identity." According to the Office, one skilled in the art uses the latter term. *Id.* Even if the Office is correct, Applicants need not confine themselves to the terminology used in the prior art as long as they make clear and precise the terms that are used to describe the invention. M.P.E.P. § 2173.05(a). Applicants note that the term % homology is adequately identified and described at pages 18-19 of the specification. One skilled in the art, upon review of the entire disclosure, would understand the metes and bounds of the term "40% homology" as it is used in claim 24.

In view of these remarks, Applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. § 112, second paragraph.

FINNEGAN  
HENDERSON  
FARABOW  
CARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
www.finnegan.com

Mark H. PAUSCH *et al.*  
Application Serial No. 08/816,011

Attorney Docket No.: 01142.0122

**CONCLUSION**

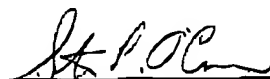
In view of the foregoing amendments and remarks, Applicants respectfully request examination on the merits and timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

By:

 *ESP. NO. 41,225*  
Antigone G. Kriss  
Reg. No. 47,721

Dated: March 12, 2003

Tel: (202) 408-4464

Fax: (202) 408-4400

Email: [antigone.kriss@finnegan.com](mailto:antigone.kriss@finnegan.com)

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
[www.finnegan.com](http://www.finnegan.com)